Friends of the Earth
Issue brief

Genetically engineered fish:

An unnecessary risk to the environment, public health and fishing communities

On November 19, 2015, the U.S. Food & Drug Administration announced its approval of the "AquAdvantage Salmon," an Atlantic salmon that has been genetically engineered to supposedly be faster-growing than other farmed salmon. This is the first-ever genetically engineered animal allowed to enter the food supply by any regulatory agency in the world. At least 35 other species of genetically engineered fish are currently under development, including trout, tilapia, striped bass, flounder and other salmon species — all modified with genes from a variety of organisms, including other fish, coral, mice, bacteria and even humans.[1] The FDA's decision on the AquAdvantage genetically engineered salmon sets a precedent and could open the floodgates for other genetically engineered fish and animals (including cows, pigs and chickens) to enter the U.S. market.

Genetically engineered salmon approved by FDA

Despite insufficient food safety or environmental studies, the FDA announced its approval of the AquAdvantage Salmon, a genetically engineered Atlantic salmon produced by AquaBounty Technologies. The company originally submitted its application to the FDA in 2001 and the FDA announced in the summer of 2010 it was considering approval of this genetically engineered fish — the first genetically engineered animal intended for human consumption. In December 2012, the FDA released its draft Environmental Assessment of this genetically engineered salmon, and approved it in November 2015. This approval was made despite the 1.8 million people who sent letters to FDA opposing approval of the so-called "frankenfish," and the 75 percent of respondents to a New York Times poll who said they would not eat genetically engineered salmon.[2] The FDA said it would probably not require labeling of the fish; however Alaska, a top wild salmon producer, requires labeling of genetically engineered salmon and momentum is growing for GMO labeling in a number of states across the U.S. and at the federal level.

The AquAdvantage Salmon was developed by artificially combining growth hormone genes from Pacific salmon and DNA from the anti-freeze genes of an eel-like ocean pout. This modification causes the production of growth hormone year-round, creating a fish that the company claims grows at twice the rate of conventionally farmed salmon.

Photo credit: E. Peter Steenstra/USFWS.

Threats to the environment

Unfortunately, the FDA's environmental assessment did not properly look at the risks genetically engineered fish pose to the environment and lacked a comprehensive analysis.

AquaBounty claims that it will only produce sterile females in order to mitigate the risks from escaped genetically engineered salmon. However, the project specifications AquaBounty submitted to the FDA only require 95 percent of the eggs produced to be sterile, meaning that up to 5 percent of the AquAdvantage Salmon produced in a commercial batch may be fertile.[3] This not only calls into question FDA's

assumption about sterility, but raises concerns about the kinds of impacts these fish may have on the environment should they escape. For example, research published in the Proceedings of the National Academy of Sciences concluded that a release of just 60 genetically engineered fish in a population of 60,000 could lead to the extinction of the wild population in less than 40 generations. At a minimum the FDA should have provided data showing how this relevant concern will not apply to this application.

Even if escaped fish are sterile they may still cause serious harm to the environment and wild fish populations. The Canadian Department of Fisheries conducted research on Coho salmon with an engineered growth hormone similar to the AquAdvantage Salmon and found that genetically engineered salmon were more aggressive when searching for food (the growth hormone made them hungrier), and in some instances resorted to cannibalism.[4] The aggressive behavior evident in genetically engineered Coho salmon led to population crashes and even the complete extinction of some wild salmon species in the study.[5]

In addition, according to the Canadian Department of Fisheries and Oceans risk assessment, the GMO salmon showed diminished growth rates in AquaBounty's commercial facilities, raising questions about the company's claims that the GMO salmon would have more accelerated growth rates.[6]

Anticipating objections to its genetically engineered fish based on the risks to the environment, AquaBounty told the FDA that it would be raising the fish in land-based fish farms. As a result, the FDA limited its environmental review to two small, land-based facilities – an egg production facility on Prince Edward Island, in Canada, and a grow-out facility in Panama where fish are raised to market size. FDA's narrow look at this application completely ignores the fact that AquaBounty has openly referred to its plans to raise genetically engineered fish all around the world.[7]

The FDA's review also ignores AquaBounty's questionable track record. In 2014, AquaBounty was fined by Panamanian regulators for failing to follow basic environmental regulations for its experimental production facility where genetically engineered salmon are being raised.[8] AquaBounty's Panamanian facility includes a record of "lost" salmon.[9] Combined with the FDA's approval granted, it will be extremely difficult to track the millions of genetically engineered fish and eggs produced as AquaBounty's operations expand. It will be equally difficult to guarantee that genetically engineered fish are raised in secure inland tanks — a reliable containment system following commercialization is just not conceivable at this time. Even in land-based facilities, farmed salmon have the ability to escape into the wild where they are virtually impossible to recover.

In addition to contaminating the gene pools of wild salmon, genetically engineered fish can spread diseases to wild populations. In 2009, AquaBounty's egg production facility on Prince Edward Island was infected with Infectious Salmon Anemia,[10] which it failed to report to the FDA.[11] ISA is an extremely deadly salmon virus that decimated the Chilean and Scottish salmon farming industries. If ISA or other diseases were to break out at genetically engineered fish farms and then those fish escaped, they could wreak havoc on wild populations. The Canadian risk assessment also suggests there are outstanding concerns about the welfare of the GMO salmon, including that they may more susceptible to *Aeromonas salmonicida*, a type of disease-causing bacteria, than non-GMO farmed salmon.[12] This suggests that there may unique animal health and environmental problems that the FDA did not fully consider.

The environmental risks genetically engineered salmon pose to oceans and fisheries should have a more thorough investigation by the FDA. The agency should have completed an Environmental Impact Statement to look at

the full range of environmental risks posed by genetically engineered salmon, including the impacts of global commercialization. In addition it should have conducted a quantitative failure mode analysis, which would assess where containment measures are most likely to fail and the impacts of such failures.[13]

Photo credit: Shutterstock.

Potential threats to human health

While data on the human health impacts of consuming genetically engineered fish is sparse, studies provide cause for concern. Genetically engineered salmon have higher levels of IGF-1 (a growth hormone that may increase risk of several types of cancer if absorbed and biologically active in the human body)[14] as compared to conventional farmed salmon.[15] There are also concerns about the possible increased risk of allergic reactions to eating genetically engineered salmon.[16]

Further concern relates to the routine use of antibiotics to control diseases often found in industrial fish farms. Farmed salmon are given more antibiotics than any other livestock by weight.[17] Some of these antibiotics are toxic to humans.[18] Given that genetically engineered salmon may be more prone to disease and deformities, they may require additional antibiotics, and eating farmed fish could mean public health risks such as allergic reactions or antibiotic resistance.[19] Unfortunately, FDA's review does not provide adequate data on the type and amount of antibiotics used in the production of AquAdvantage Salmon.

The FDA has nonetheless decided these fish are safe to eat based solely on data provided by AquaBounty, whose sample sizes were as small as six to 12 fish.[20] This is bad science and bad food.

Lack of federal regulation of genetically engineered fish and animals

Unfortunately, there are currently no U.S. laws specifically governing the production and sale of genetically engineered animals. Instead, the FDA regulates genetically engineered animals as "new animal drugs," using laws written well before the advent of genetic engineering for such things as chicken feed additive and cow vaccines. To receive FDA approval to sell a genetically engineered fish for human food, producers must complete a New Animal Drug Application.[21]

Approving a genetically engineered animal for food under the banner of a "drug" is extremely problematic. First, animal drug laws were not written to regulate living organisms that can reproduce and move of their own accord — both of which genetically engineered animals can do. Second, the new animal drug approval process is confidential and mostly closed to the public until complete, due to confidential information laws for drug products, severely limiting public participation in the regulatory process.

Instead of relying on antiquated laws for regulating animal drugs, the FDA must develop new regulations that are specific to genetically engineered animals and take into account the risks GE animals pose to the environment, human health and related socio-economic concerns.

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Put the brakes on genetically engineered salmon

The FDA must put the brakes on allowing genetically engineered salmon onto the market until it conducts a comprehensive and independent Environmental Impact Statement, and until proper regulations are in place to deal with the novel risks to human health and the environment posed by genetically engineered fish and other genetically engineered animals.

Friends of the Earth strongly opposes the approval and commercialization of genetically engineered fish, and continues to advocate that grocery stores and retailers not sell GMO salmon, regardless of the FDA's approval. It is also critical that the FDA require clear and mandatory labeling in order to allow consumers to make informed purchasing decisions.

How to get involved

Visit our website at www.foe.org/gefreeseafood where you can download campaign materials and read about ways to take action.

You can also write to your favorite grocery stores, restaurants and chefs and ask them to join the **Campaign for GE-Free Seafood**. Visit the website at www.gefreeseafood.org to learn more!

Companies can also visit www.gefreeseafood.org to learn more about the **Pledge for GE-Free Seafood** and why grocery stores, restaurants and chefs should sign the pledge!

GE-Free Seafood

www.gefreeseafood.org

[1] Genetically Engineered Fish. Rep. Center for Food Safety, Jan. 2013. <http://www.centerforfoodsafety.org/wp-content/uploads/2013/01/ge-salmon-fact-sheet.pdf>.

[2] Kopicki, Allison. "Strong Support For Labeling Modified Foods." *The New York Times.* July 27, 2013. <http://www.nytimes.com/2013/07/28/science/strong-support-for-labeling-modified-foods.html?_r=1>.

[3] Food and Drug Administration-VMAC Briefing Packet, 2010, p.128.

[4] Devlin, R. H., Mark D'Andrade, Mitchell Uh, and Carlo A. Biagi."Population Effects of Growth Hormone Transgenic Coho Salmon Depend on Food Availability and Genotype by Environ- ment Interactions."Proceedings of the National Academy of Sciences 101.25 (2004): 9303-308.

[5] Ibid.

[6] "Environmental and Indirect Human Health Risk Assessment of the AquAdvantage salmon." Office of Aquatic Biotechnology, Department of Fisheries and Oceans Canada. July 2, 2013. http://webiva-downton.s3.amazonaws.com/877/47/1/5797/Canadian_Environmental_Assessment_Scanned.pdf

[7] Pollack, Andrew."Engineered Fish Moves a Step Closer to Approval."New York Times, 21 Dec. 2012.

[8] AquaBounty Technologies. "[Press Release]. AquaBounty responds to misleading claims made by anti-GM organizations" October 28, 2014.

[9] LeVaux, Ari. "The Genetically Engineered Salmon That Could Soon Run Wild". Outside. June 6, 2012. <http://www.outsideonline.com/1900276/genetically-engineered-salmon-could-soon-run-wild>.

[10] "AquaAdvantage® Salmon Draft Environmental Assessment."Page 43.

[11] Entine, John."Genetically Modified Salmon: AquAdvantage FDA Assessment Is Delayed Possibly by the White House."Slate, 19 Dec. 2012.

[12] "Environmental and Indirect Human Health Risk Assessment of the AquAdvantage salmon." Office of Aquatic Biotechnology, Department of Fisheries and Oceans Canada. July 2, 2013. <http://webiva-downton.s3.amazonaws.com/877/47/1/5797/Canadian_Environmental_Assessment_Scanned.pdf>.

[13] Kapuscinski, Anne, and Fredrik Sundström. Comments on Environmental Assessment for AquAdvantage Salmon and Briefing Packet on AquAdvantage Salmon for the Veterinary Medicine Advisory Committee.
[14] Yu H. and T. Rohan."Role of the Insulin-Like Growth Factor Family in Cancer Development and Progression."Journal of the National Cancer Institute, vol. 92, iss. 18. September 20, 2000; and Moschos, S. and C. Mantzoros."The Role of the IGF System in Cancer: From Basic to Clinical Studies and Clinical Applications."Oncology, vol. 63 iss. 4. November 4, 2002.
[15] Hansen, Michael. Comments of Consumers Union on Genetically Engineered Salmon, Food and Drug Administration Docket No. FDA-201034-N-0001, Veterinary Medicine Advisory Committee Meeting. Rep. Consumers Union, 16 Sept. 2010. Web. <http://www.consumersunion.org/pdf/CU-comments-GE-salmon-0910.pdf>.
[16] Ibid.
[17] "Farmed Salmon Facts."Wild Pacific Salmon LLC.
[18] Rebecca Goldberg and Tracy Triplett. Murky Waters: The Environmental Effects of Aquaculture in the U.S. (p 44). Environmental Defense Fund (1997).
[19] Hernández Serrano, Pilar. and Food and Agriculture Organization of the United Nations and Food and Agriculture Organization of the United Nations. Fish Utilization and Marketing Service Responsible use of antibiotics in aquaculture / by Pilar Hernández Serrano FAO, Rome: 2005.
[20] Ibid.
[21] Packet – AquaAdvantage Salmon,"Food and Drug Administration, Center for Veterinary Medicine.